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10/589,975	07/11/2007	Isabelle Hansenne	293093US0PCT	2369
22850 7590 03/15/2011 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER KISHORE, GOLLAMUDI S				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/589,975

Applicant(s)

HANSENNE ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-11 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-040)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The amendment dated 2-28-11 is acknowledged.

Claims included in the prosecution are 1, 4-11 and 13.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 4-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harding (US 5,705,144) by itself or in combination with Reynolds (5,431,911).

Harding et al. teaches a composition to lighten the skin and the repair of photo-damaged skin comprising a dioic acid having the general structure of $\text{COOH}-(\text{CaHb})-\text{COOH}$, where a is an integer from 6 to 20 and b is an integer from 8 to 40 (see abstract and col. 2, lines 10-26). The compound 8-hexadecene-1, 16-dicarboxylic acid is a species of the dioic acid of Harding et al. where a is 16 and b is 30. The compositions further contain a hydroxy acid. According to Harding, the composition is topically applied to human skin to repair photo-damaged skin and to prevent photo-damage to skin due to exposure to sunlight, to reduce skin blotchiness and mottling due to hyperpigmentation, to improve skin texture with reductions in fine wrinkling and to treat actinic

damage to all epidermal cells (col. 11, lines 31-42). Although Harding does not teach as to how long the composition has to be applied, since the composition is for topical application, it would have been obvious to one of ordinary skill in the art to keep the formulation on the skin to achieve the desired purpose. Rinsing the composition off of the skin is within the skill of the art of cosmetics since cosmetic compositions such as sunscreens are rinsed routinely. Such a skill is also evident from Reynolds which teaches the application of the skin compositions to protect it against dryness and wrinkles for 20 minutes and removing the composition by a cold water rinse (abstract, col. 1, lines 55-62; col. 3, lines 49-66). The criticality of the amounts of 8-hexadecene-1, 16 dicarboxylic acid and the beta-hydroxy acid is unclear to the examiner since the amounts depend upon the condition to be treated and thus, a manipulatable parameter.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Harding relates to the reduction of melanin production and points out to col. 12. According to applicant therefore, Harding's teachings are that the dioic acids are to be applied to effectuate a biological mechanism and not chemical one as is a chemical scrubbing process claimed. These arguments are not found to be persuasive. First of all, applicant is incorrect in stating that Harding teaches only the reduction of melanin production. On col. 11, lines 31-42, Harding clearly teaches that the composition is applied to improve skin texture with reductions in fine wrinkling and to treat actinic damage to all epidermal cells, besides inhibition of melanin which according to applicant is a biological process. According to instant claim 1, the process involves topically applying the composition, leaving the composition for specific time and

removing the composition by rinsing. Mechanism by which the composition achieves this process has no significance since Harding teaches applying the composition to the skin. Secondly, instant claims are drawn to treating one skin irregularity and one such irregularity is pigmentary mark. Since skin pigmentary marks are caused by melanin, it would have been obvious to one of ordinary skill in the art that pigment marks would be removed by using the composition since Harding teaches that that melanin production is reduced without affecting the cell viability which applicants themselves recognize. Applicant's arguments that the examiner simply concludes that either it is well known to rinse off a composition or relies on Reynolds for this step in the claim and that a composition that is to be applied and effect a biological mechanism may need the composition to be kept on the skin and it would not be intended to be rinsed off are not persuasive since as pointed out above, Harding teaches even removal of fine wrinkles. Therefore, the amount of time the composition is kept on the skin is a manipulatable. Applicants have not shown any criticality of the time range claimed. Furthermore, a careful review of instant specification indicates, the claimed process only increases the trans-epidermal water loss as compared to glycolic acid and nothing else.

With regard to applicant's argument that there is simply no teaching in Harding that the concentration of 8-hexadecene dicarboxylic acid in a chemical scrubbing process is a variable requiring optimization, the examiner points out once again, the only process which is biological according to applicant is the inhibition of melanin; Harding teaches even removal of wrinkles by topical application. Furthermore, as pointed out above, instant process steps do not require scrubbing. The examiner also

points out that instant specification does not define 'scrubbing' and page 7 of the specification only states that the composition may be applied to the face etc by any means allowing uniform distribution and especially using cotton wool, a cotton bud, a brush, a gauze, a spatula or a pad --- and may be removed by rinsing with water.

3. Claims 8-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harding (US 5,705,144) by itself or in combination with Reynolds (5,431,911) as set forth above, further in view of Jones (US 2004/0126352).

The teachings of Harding and Reynolds have been discussed above. Harding does not specify that the hydroxy acid to be a salicylic acid.

Jones while disclosing compositions for treating facial wrinkles teaches that hydroxy acids such as octanoylsalicylic acid and octylsalicylic acids are anti-wrinkle agents. The composition is applied for a period of time sufficient to improve the aesthetic appearance of skin. (0002, 0029 and 0042 and claim 3).

To include a salicylic acid derivative such as octanoylsalicylic acid in Harding with the expectation of obtaining at least an additive effect would have been obvious to one of ordinary skill in the art since Jones teaches that salicylic acids are anti-wrinkle agents. The criticality of the amounts of 8-hexadecene-1, 16 dicarboxylic acid and the beta-hydroxy acid is unclear to the examiner since the amounts depend upon the condition to be treated and thus, a manipulatable parameter.

4. Claims 1, 4-7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Research disclosure # 477 in combination with Internet article 002301860(both

are of record) and Reynolds (5,431,911), optionally in further combination with Harding (5,705,144) cited above.

The research disclosure teaches that Arlatone Dioic DCA works through PPAR gamma ligands and this compound is for anti-aging, skin lightening, age spot reduction and acne (page 3 of the article). The amounts taught by the disclosure are 0.0001 to 10 %.

The internet article discloses that the product of Arlatone Dioic DCA is available in the market and can be used for day and night creams and skin treatment systems (Table 2).

These references however, do not teach the leaving the composition on the skin for a period of 5 minutes to 6 hours and rinsing the composition.

Reynolds teaches the application of the skin compositions to protect it against dryness and wrinkles for 20 minutes and removing the composition by a cold water rinse (abstract, col. 1, lines 55-62; col. 3, lines 49-66).

To leave the composition containing Arlatone Dioic DCA on the skin for sufficient period and then rinse it off to treat skin blemishes would have been obvious to one of ordinary skill in the art since the Internet article teaches that this compound can be formulated in day and night creams and Reynolds teaches that such a method of removing wrinkles is routinely practiced in the art. Since Harding teaches that dioic acid lightens the skin, it would have been obvious to one of ordinary skill in the art that the composition would even remove pigmentary marks and scars.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the research disclosure teaches a composition comprising from 0.0001 to 10 % of dioic acid that is useful for day and night creams and contrary to the examiner's contention are intended to be kept on the skin and not to be rinsed off; in contrast the scrubbing process presently claimed require high amounts of dioic acid and that is why rinsing off the composition is needed after application. Further according to applicant, the cited document encourage to use low amounts of dioic acid and accordingly the one skill (sic) in the art would not have been motivated to rinse off the composition as described in Reynolds.

These arguments are not persuasive. First of all, the research disclosure, 477 teaches in the paragraph bridging pages 2 and 3 that the concentration of octadecenedioic acid depends upon the particular effect to be achieved and according to 477, this amount is from 0.01 to 40 %. Applicant's arguments that claims 6 and 7 recite the amounts which exceed the amounts taught by 477 are not persuasive. The internet article 860 teaches not just foundation creams and powders, but also a wide range of skin products which include body wash and creams (page 2). Since one uses a body wash or creams for only a short time, instant 5 minutes to 30 minutes would have been obvious to one of ordinary skill in the art. Furthermore, as pointed out above, applicant has not established the criticality of the time periods.

4. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Research disclosure # 477 in combination with Internet article 002301860(both are of

record) and Reynolds (5,431,911) as set forth above, further in view of Jones (US2004/0126352).

The teachings of Research disclosure, Internet article and Reynolds have been discussed above. What is lacking in these references is the use of salicylic acid.

Jones while disclosing compositions for treating facial wrinkles teaches that hydroxy acids such as octanoylsalicylic acid and octylsalicylic acids are anti-wrinkle agents. The composition is applied for a period of time sufficient to improve the aesthetic appearance of skin. (0002, 0029 and 0042 and claim 3).

To include a salicylic acid derivative such as octanoylsalicylic acid in compositions containing Arlatone Dioic DCA with the expectation of obtaining at least an additive effect would have been obvious to one of ordinary skill in the art since Jones teaches that salicylic acids are anti-wrinkle agents. The criticality of the amounts of 8-hexadecene-1, 16 dicarboxylic acid and the beta-hydroxy acid is unclear to the examiner since the amounts depend upon the condition to be treated and thus, a manipulatable parameter.

Applicant's arguments have been fully considered, but are not found to be persuasive. The examiner has already addressed applicant's arguments pertaining to 477, 860 and Reynolds. Applicant does not provide any specific argument regarding Jones. The rejection is maintained.

5. Claims 1, 4-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 101 50 734 (English equivalent, US 2005/0008665) of record by

itself or in combination with Reynolds (5,431,911), optionally in further combination with Harding.

DE teaches cosmetic compositions for the treatment of skin changes such as unwanted pigmentation, hyper pigmentation, local hyper pigmentation and faulty pigmentation by application of a composition containing 8-hexadecene-1, 16 dicarboxylic acid. The amount to be applied is from 0.001 % to 10 % (Abstract; 0002-0003; 0006; 0064; 0074 of English equivalent). The compositions further contain a salicylate (0088). Although DE does not teach as to how long the composition has to be applied, since the composition is for topical application, it would have been obvious to one of ordinary skill in the art to keep the formulation on the skin to achieve the desired purpose. Rinsing the composition off of the skin is within the skill of the art of cosmetics since cosmetic compositions such as sunscreens are rinsed routinely. Such a skill is also evident from Reynolds which teaches the application of the skin compositions to protect it against dryness and wrinkles for 20 minutes and removing the composition by a cold water rinse (abstract, col. 1, lines 55-62; col. 3, lines 49-66). The criticality of the amounts of 8-hexadecene-1, 16 dicarboxylic acid and the beta-hydroxy acid is unclear to the examiner since the amounts depend upon the condition to be treated and thus, a manipulatable parameter.

6. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 101 50 734 (English equivalent, US 2005/0008665) by itself or in combination with Reynolds (5,431,911) as set forth above, further in view of Jones (US2004/0126352).

The teachings of DE and Reynolds have been discussed above.

Jones while disclosing compositions for treating facial wrinkles teaches that hydroxy acids such as octanoylsalicylic acid and octylsalicylic acids are anti-wrinkle agents. The composition is applied for a period of time sufficient to improve the aesthetic appearance of skin. (0002, 0029 and 0042 and claim 3).

To include a salicylic acid derivative such as octanoylsalicylic acid in Harding with the expectation of obtaining at least an additive effect would have been obvious to one of ordinary skill in the art since Jones teaches that salicylic acids are anti-wrinkle agents. The criticality of the amounts of 8-hexadecene-1, 16 dicarboxylic acid and the beta-hydroxy acid is unclear to the examiner since the amounts depend upon the condition to be treated and thus, a manipulatable parameter. Since Harding teaches that dioic acid lightens the skin, it would have been obvious to one of ordinary skill in the art that the composition would even remove pigmentary marks and scars.

Applicant's arguments for the above rejections have been fully considered, but are not persuasive. Applicant argues that DE broadly teaches a composition comprising 0.0001 to 10 % of dioic acid but clearly when considering the entirety of the teachings of DE the amounts to be used are significantly less. This argument is not persuasive since DE is suggestive of 10 % and the rejection is a 103 rejection. The lower limit in claim 6 is 10 % and lower limit in claim 7 is 15 % which is closer to 10 % taught by DE and applicant has not shown any criticality of the amounts. The examiner also points out that DE teaches topical compositions with effective concentrations (see 0082 of English equivalent). With regard to applicant's arguments that DE's teachings would not have

motivated to rinse of the composition as concluded in the rejection with or without Reynolds, that is useful for day and night creams and contrary to the examiner's contention are intended to be kept on the skin and not to be rinsed off, the examiner points out that DE even teaches 'cleansing milk' in 0084 and 0144 of English equivalent.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571)272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK